

REMARKS/ARGUMENTS

In response to the Office Action mailed November 7, 2005, Applicants provide the following response along with a Request for Continued Examination.

Claims 32-50 are presently pending. Claims 44, 45 and 47-50 have been canceled and claims 38, 43 and 46 have been amended. Applicants respectfully submit new claims 51-56 to overcome the rejection of claims 44, 47 and 49. No new matter was introduced in the new claims.

Claim Objections

Claim 46 was objected to for being misnumbered and claim 46 has been renumbered as claim 47.

Applicant was advised that claims 46-50 are substantially duplicates of claims 43-45. Claims 49 and 50 have been canceled and applicant will cancel additional claims, if necessary, in a future response.

Claim Rejections under 35 U.S.C. §112

Claims 44, 45 and 47-50 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have canceled claims 44, 45 and 47-50 and amended claims 43 and 46 to read, in part, "said mPEGMA comprises mPEGMA of at least three different molecular weights" to more clearly claim that which Applicants consider their invention.

Additionally new claims 51-56, dependent from amended claims 43 and 46, have been added to clarify that three exemplary mPEGMA's are a high molecular weight mPEGMA having a molecular weight of 1100, a medium molecular weight mPEGMA having a molecular weight of 526 and a low molecular weight mPEGMA having a molecular weight of 360.

Applicants respectfully request that the rejections of claims under 35 U.S.C. §112, second paragraph be withdrawn in light of the claim amendments presented *supra*.

Claim Rejections under 35 U.S.C. §103

The Examiner has rejected claims 32-50 under 35 U.S.C. §103(a) as being unpatentable over Yang et al (USPN 5,803,925 "Yang") in view of Luthra et al. (USPN 6,287,707 "Luthra"). The Applicants respectfully disagree.

The Examiner states that Yang teaches an intraocular lens inserter cartridge comprising lubricious coatings *covalently bound* to at least one IOL-contacting surface of the IOL inserter cartridge. However, Yang fails to teach a second substituent component effective to reduce hydrolysis of the lubricity enhancing group.

The Examiner states that Luthra teaches methoxy polyethylene glycol methacrylate coatings are suitable for providing medical devices with biocompatible, lubricious hydrophilic coatings.

Based on these teachings the Examiner concluded that it would have been obvious for a skilled artisan to combine these references to arrive at the presently claimed invention and that the skilled artisan would have considered Yang and Luthra analogous insofar as both references are concerned with forming biocompatible, lubricious hydrophilic coatings on medical devices for insertion into human bodies (sic). It is noted that Yang does not teach medical device for insertion into human bodies, but rather teaches providing *ex vivo* devices for inserting medical devices in to human bodies, a relevant distinction, but not the primary basis for the argument that follows.

The Examiner does not state his basis for what would have motivated a skilled artisan to combine Yang and Luthra, and in fact the Examiner does not directly address this essential element of a *prima facie* case of obviousness. The Court of Appeals for the Federal Circuit as well as the MPEP at § 2143.01 specifically state that a *prima facie* case of obviousness is not established unless the Examiner demonstrates some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. Thus, absent some showing of a motivation to combine the references a *prima facie* case of obviousness cannot be maintained. Merely stating that Yang and

Luthra are "analogous" is not a sufficient showing of a motivation to combine. However, while certainly relevant, this fact alone it is not the basis for the Applicant's argument.

In fact the Applicants respectfully assert that the Examiner cannot argue a motivation to combine the cited references and as will be abundantly clear from the argument that follows, person skilled in the relevant art would conclude that Luthra *teaches away from Yang and the present invention*. Therefore, no basis for combining Luthra with Yang exists. Thus, no *prima facie* case of obviousness can be maintained based on Yang in view of Luthra.

It is well settled that it is improper for an Examiner to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Such is clearly the present case. The Examiner's attention is directed to Luthra at column 1 lines 38-49 and at column 2 lines 2-13 (reproduced below for the Examiners convenience).

"It has been well recognized that polyethylene oxide (PEO) (also called polyethylene glycol or PEG) when bound to a medical device offers good biocompatibility, lubricity and hydrophilicity. U.S. Pat. No. 4,424,311 discloses a polymerizable PEO monomer having polyethylene oxide unit with a carbon-carbon double bond which is grafted on to PVC or vinyl chloride-vinyl acetate copolymer or vinyl chloride-vinyl acetate-ethylene terpolymer. *Disadvantages of grafting PEO are that it is a lengthy procedure and the grafted PEO units are unevenly distributed*. Therefore, homogenous coverage on the surface is not achieved, which results in reduced biocompatibility and lubricity." (Luthra at column 1 lines 38-49 Emphasis added)

Further:

"It is an object of the present invention to mitigate or overcome some of the aforementioned disadvantages encountered in the prior art.

The present invention is concerned with biocompatible, lubricious, hydrophilic materials suitable for use in medical devices or otherwise. *It is proposed that the materials may be used to coat a substrate such as a medical device or may be blended into a polymer composition prior to formation of the medical device or other article*. The invention extends to polymers, their production methods, and their uses as coatings or components of articles of manufacture." (Luthra at column 2 lines 3-13 Emphasis added)

Thus Luthra *expressly* teaches that one problem with prior art coatings, and a problem sought to be solved by Luthra, was the *disadvantages of grafting PEO* to the surface of a medical device. This is completely contra to the teachings of both the present invention and Yang. Therefore no motivation to combine Yang and Luthra vis-à-vis the present invention exists and no *prima facie* case of obviousness can be maintained by attempting to combine Yang and Luthra.

To elaborate, the present inventors (and the present assignees of the Yang patent) realized that the Yang coating had a less than optimal shelf life primarily because the *covalent bound* (i.e. grafted) PEG coatings were hydrolyzed. While investigating methods for improving the Yang coatings the present inventors surprisingly discovered that by providing the lubricity enhancing group (PEG) molecule *covalently bound* to the medical device surface with a substituent that reduces hydrolysis, such as for example a terminal methoxy group, shelf life unexpectedly improved considerably without a corresponding loss of lubricity.

Thus, the present inventors were concerned with improving Yang. The assignee of the present invention, Advanced Medical Optics, has lubricous coating that are not covalently bound, these have proven problematic due to transfer of the non-grafted coating onto the surface of the intraocular lens (IOL) when passed thorough an inserter during the IOL insertion process. See the present application at paragraph [00009] of US patent application publication number 2004/0267359 (the publication of the present application, reproduced below for the Examiner's convenience).

"While many of the prior art lubricity enhancing components are generally satisfactory, further improvements are desirable. For instance, in inserters having non-covalently bonded GMS-based lubricity enhancing components such as those disclosed in the aforementioned Makker et al. patent, the blooming process may continue even after exposure of the inserter interior wall to high temperatures has stopped, which can eventually result in excessive amounts of GMS on the surface of interior wall. Such inserters have the potential of causing excess GMS to be transferred onto the surface of an IOL optic during insertion, causing unsightly blemishes or streaks on the optic."

Luthra, in dramatic contrast to the teachings of both Yang and the present invention, specifically states that covalent bonding, or grafting, the lubricous materials to the surface of a medical device results in an inferior coating, whereas the present invention specifically teaches the exact opposite, that non-covalently linked, or grafted, coating are unsatisfactory for use in the disclosed application. This in turn goes back to the aforementioned inadvertent mischaracterization of Yang wherein the Examiner states that Yang teaches coatings for medical devices intended for use within the body. However, unlike Luthra, which does teach coatings for devices used *in vivo*, Yang and the present invention are directed at *ex vivo* devices associated with optically clear medical devices where the transfer of *non-covalently linked coating* to the surface of the optically clear lens renders the lens unusable. Thus, Luthra and Yang are not truly analogous art. It is entirely unlikely that persons skilled in the art of making *ex vivo* medical devices used in association with optically clear lenses, where *non-covalently linked lubricous coating* have proven to be less than optimum, would seek the teaching of Luthra where *covalently bonded coatings are taught as unacceptable and instead teaches the superiority of non-covalently bonded or grafted coatings*.

Thus to establish a *prima facie* case of obviousness, three basic criteria must be met. *First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings*. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (Emphasis added). In the present case, the Examiner has not expressly stated his reasons for asserting that there would be motivation to combine Luthra with Yang. More importantly, it would be futile to make such an assertion because Luthra clearly teaches away from the present invention and the primary reference Yang. Persons having ordinary skill in the art seeking to solve the

problem confronted by the present invention would not seek the teachings of a reference that teach methods the inventor deliberately sought to avoid, both in the present invention and in their own previous efforts as discussed in Yang and the present application.

Therefore, in conclusion, the applicants respectfully assert that the Examiner has not met his burden of establishing a *prima facie* case of obviousness because he has not established a motivation to combine the secondary reference Luthra with Yang. Moreover, the applicant assert that due to the clear teaching away expressly stated in Luthra, there is no reasonable basis for asserting Luthra in combination with Yang.

Applicants respectfully request that the rejections of claims under 35 U.S.C. §103(a) be withdrawn in light of the arguments presented *supra*.

Conclusions

Applicants have properly and fully addressed the Examiner's grounds for rejection. Applicants respectfully submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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